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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,137	09/12/2003	Jeffrey R. Fine	18205-00002	9088

7590 12/19/2006

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EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	PAPER NUMBER
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/19/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/662,137	FINE	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-20 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

In view of the application of a new art rejection under 35 U.S.C. 103, PROSECUTION IS HEREBY REOPENED. An Action is set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

In the last Office Action claims 1-20 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. It was asserted the claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention with respect to the recitation in claims 1 and 13 "relieving the potential for" symptoms of ear and sinus cavity blockage.

The recitation in claims 1 and 13 "relieving the potential for" is not literally found in the disclosure. However, upon reconsideration, the specification provides support for the potential therapy. Accordingly, the rejection of record under 35 U.S.C. 103 is withdrawn.

Applicant's arguments with respect to claims 1-20 that were rejected under 35 U.S.C. 103(a), as being unpatentable over both Jones et al., American Journal of Emergency Medicine, and Singletary et al., American Journal of Emergency Medicine, in the last Office Action have been considered but are moot in view of the new grounds of rejection.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singletary et al., American Journal of Emergency Medicine, and Dawson, A.G., Textbook of Travel Medicine, in view of the PDR for Nonprescription Drugs.

Singletary teaches combination therapy in the form of **both** systemic and topical decongestants to treat a patient suffering from symptoms of sinus cavity blockage during airline descent. See the abstract, page 329, and the first column, first paragraph, on page 331.Dawson teaches the middle ear to be the most common site of barotrauma that almost exclusively is a problem during aircraft descent. Dawson states the appropriate treatment includes decongestant medication. See Table 31-1 on page 394, where pseudoephedrine (60 mg) is the only decongestant depicted. Oxymetazoline is depicted as a nasal spray/drops for treatment of barotrauma. The pharmacology of both pseudoephedrine and oxymetazoline are well known in the prior art. The present specification teaches equivalence among the recited decongestants in alleviating

symptoms of ear and sinus cavity blockage in a descending aircraft. See page 6, line 22. The peak plasma concentration of pseudoephedrine is reached after 0.5 to 2 hours. According to the PDR, the onset of action of oxymetazoline spray (0.05%) is within just a few minutes, and temporary relief of nasal congestion continues for up to 12 hours. Therefore, in view of the combined teachings of the prior art, the skilled artisan in travel medicine would have been motivated to prepare a combination therapy comprising the oral decongestant pseudoephedrine to be administered one hour prior to decent, followed by the nasal administration of oxymetazoline later in flight, with a reasonable expectation of relieving the potential for symptoms of ear and sinus cavity blockage in a descending aircraft. Such combination therapy and mode of administration would have been obvious because, according to known pharmacokinetic properties of pseudoephedrine, the time generally required for its absorption, distribution and peak plasma concentration is approximately one hour. The decongestant effect of oxymetazoline is almost immediate and lasts for up to 12 hours. Accordingly, in view of the pharmacokinetic profiles of both pseudoephedrine and oxymetazoline, one skilled in the art would have been motivated to prepare a kit comprising an oral decongestant having a peak plasma concentration in 0.5 to 2 hours, along with a nasal spray decongestant that is essentially immediate-acting, with a strong expectation of relieving potential ear and sinus blockage that occurs on aircraft descent. It would have been reasonable to expect both decongestants to be most therapeutically efficacious at the time barotrauma occurs.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The recitation "including at least the nasal lining" in claims 1 and 10 is indefinite. It is unclear whether or not a claim limitation is intended.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phyllis Spivack

December 9, 2006

Phyllis G. Spivack

PHYLLIS SPIVACK
PRIMARY EXAMINER

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

Ardin H. Marschel 12/10/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER

Ardin Marschel

SPE 1614